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10/720,765	11/24/2003	James Martucci	EIS-5799 DIV.1	4921
29290 7590 05/12/2009 BAXTER HEALTHCARE CORPORATION 1 BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015				
EXAMINER MORGAN, ROBERT W				
ART UNIT		PAPER NUMBER		
3626				
NOTIFICATION DATE		DELIVERY MODE		
05/12/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

**Application No.**

10/720,765

**Applicant(s)**

MARTUCCI ET AL.

**Examiner**

ROBERT W. MORGAN

**Art Unit**

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 2/6/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Notice to Applicant***

1. This communication is in response to the amendment filed 2/26/09. Claims 1 and 5-6 have been amended. Claims 1 and 3-6 are presented for examination.

***Claim Objections***

2. Claim 6 is objected to because of the following informalities: line 21, reads "(h)" should read "(e)". Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(c) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1 and 3-6 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,671,563 to Engelson et al.

As per claim 1, Engelson et al. teaches a method for medication delivery comprising the steps of:

(a) providing a medication container containing a prescribed medication and a first label containing data on the prescribed medication and instruction of delivering of the medication, the prescribed medication data and the instruction of delivering the medication being provided in machine readable format is met by the order transmitted to the institution's pharmacy which is processed and generally includes the patient's name, the drug name, and the appropriate treatment parameters are represented on the label (182, Fig. 5) affixed to container (see: column 13, lines 3-21);

(b) providing a tag adapted to be worn by a patient, the tag having a second label containing data of the patient, the patient data being provided in machine readable format (see: column 7, lines 48-51 and Fig. 5A);

(c) providing a handheld computing device (In another embodiment, the care management system is a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50)) with:

means for reading the prescribed medication data and medication delivery instruction from the first label and patient data from the second label is met by barcodes (182, Fig. 5) and (175, 5A) being read by barcode reader (68, Fig. 2) (see: column 7, lines 48-54 and column 8, lines 12-19);

means for storing the data and instruction (46, Fig 2) (see: column 19-24);

means for communicating data and instruction to other electronic devices is met by the file server that includes communication hardware for communicating with the hospital network (see: column 5, lines 25-32);

(d) the handheld computing device reading the prescribed medication data and medication delivery instruction from the first label and storing the prescribed medication data and medication delivery instruction is met by the barcode (182, Fig. 5) being read by a barcode reader (see: column 8, lines 12-19). In addition, care management (30, Fig. 1-2) includes a file server (45, Fig. 1-2) such as personal computers having sufficient mass storage (46, Fig. 1-2), such as local hard drives, CD ROM, magnetic tape, or other media (see: column 5, lines 19-22). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50);

(e) the handheld computing device reading the patient data from the second label and storing the patient data is met by the care management system (30, Fig. 2) reading barcode (182, Fig. 5) and patient bracelet (170, Fig. 5A) using a barcode reader to ensure that the right drug is delivered to the right patient at the right time in the right manner (see: column 8, lines 12-19). In addition, care management (30, Fig. 1-2) includes a file server (45, Fig. 1-2) such as personal computers having sufficient mass storage (46, Fig. 1-2), such as local hard drives, CD ROM, magnetic tape, or other media (see: column 5, lines 19-22). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50);

(f) the handheld computing device comparing the stored prescribed medication data to the stored patient data and confirming a match between the stored prescribed medication data and the stored patient data is met by the care management system (30, Fig. 2) reading barcode (182, Fig. 5) and patient bracelet (170, Fig. 5A) using a barcode reader to ensure that the right drug is delivered to the right patient at the right time in the right manner (see: column 8, lines 12-19); and

(g) the handheld computing device communicating the stored medication delivery instruction from the first label to a medication delivery device is met by the care management system (30, Fig. 15) including a pharmacy CPU, the nurse station nursing CPU (70, Fig. 15) and bedside CPUs and clinical devices which are usually connected by Ethernet cabling can be eliminated (see: column 15, lines 35-39). In addition, care management (30, Fig. 1-2) includes a file server (45, Fig. 1-2) such as personal computers having sufficient mass storage (46, Fig. 1-2), such as local hard drives, CD ROM, magnetic tape, or other media (see: column 5, lines 19-22). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50). Engelson et al. also teaches that care management system automatically downloads medication information from the pharmacy CPU (60, Fig. 2) through the local area network (50, Fig. 2) into the bedside CPU (80, Fig. 2) and then into the infusion pump (92, Fig. 2) (see: column 14, Fig. 2) (see: column 14, lines 4-13). In addition, the infusion pump (92, Fig. 2) can be attached to the bedside CPU (80, Fig. 2) (see: column 14, line 6), suggesting that the infusion pump and bedside CPU are one unit.

(h) the medication delivery device storing the medication delivery instruction and delivering the medication to the patient is met by the care management system (30, Fig. 15) including a pharmacy CPU, the nurse station nursing CPU (70, Fig. 15) and bedside CPUs and clinical devices which are usually connected by Ethernet cabling can be eliminated (see: column 15, lines 35-39). In addition, care management (30, Fig. 1-2) includes a file server (45, Fig. 1-2) such as personal computers having sufficient mass storage (46, Fig. 1-2), such as local hard drives, CD ROM, magnetic tape, or other media (see: column 5, lines 19-22). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50).

As per claim 3, Engelson et al. teaches the claimed step of the medication delivery device performing periodic checks of the operating parameters of the medication delivery device against the medication delivery instruction downloaded from the handheld computing device to ensure the operating parameters are within the ranges set by the medication delivery instruction after starting the delivery of the medication. This feature is met by the medical administrative management module (110, Fig. 3) that automatically records the start time of the infusion, queries the pump periodically throughout the infusion and maintains a continuous log of the infusion and the volume infused in a patient MAR (see: column 8, lines 41-47). Furthermore, the medical administrative management module (110, Fig. 3) is implemented using the invention's hardware system (see: column 8, lines 34-36).

As per claim 4, Engelson et al. teaches the claimed the first label is encoded with the prescribed medication data and the instruction of delivering the medication derived from a print stream generated from a pharmacy information system. This limitation is met by the order

transmitted to the institution's pharmacy which is processed and generally includes the patient's name, the drug name, and the appropriate treatment parameters are represented on the label (182, Fig. 5) affixed to container (see: column 13, lines 3-21).

As per claim 5, Engelson et al. teaches a method for medication delivery comprising the steps of:

(a) providing a medication container containing a prescribed medication and a first label containing data on the prescribed medication and instruction of delivering of the medication, the prescribed medication data and the instruction of delivering the medication being provided in machine readable format is met by the order transmitted to the institution's pharmacy which is processed and generally includes the patient's name, the drug name, and the appropriate treatment parameters are represented on the label (182, Fig. 5) affixed to container (see: column 13, lines 3-21);

(b) providing a tag adapted to be worn by a patient, the tag having a second label containing data of the patient, the patient data being provided in machine readable format (see: column 7, lines 48-51 and Fig. 5A);

(c) providing a handheld computing device (In another embodiment, the care management system is a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50)) with:

means for reading the prescribed medication data and medication delivery instruction from the first label and patient data from the second label is met by barcodes (182, Fig. 5) and (175, 5A) being read by barcode reader (68, Fig. 2) (see: column 7, lines 48-54 and column 8, lines 12-19);



means for storing the data and instruction is met by (46, Fig 2) (see: column 19-24);

means for communicating data and instruction to other electronic devices is met by the file server that includes communication hardware for communicating with the hospital network (see: column 5, lines 25-32);

(d) the handheld computing device reading and storing the prescribed medication data and medication delivery instruction from the first label is met by the barcode (182, Fig. 5) being read by a barcode reader (see: column 8, lines 12-19). In addition, the care management system (30, Fig. 1-2) includes a file server (45, Fig. 1-2) such as personal computers having sufficient mass storage (46, Fig. 1-2), such as local hard drives, CD ROM, magnetic tape, or other media (see: column 5, lines 19-22). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50);

(e) the handheld computing device reading and storing the patient data from the second label is met by the care management system (30, Fig. 2) reading barcode (182, Fig. 5) and patient bracelet (170, Fig. 5A) using a barcode reader to ensure that the right drug is delivered to the right patient at the right time in the right manner (see: column 8, lines 12-19). In addition, the care management system (30, Fig. 1-2) includes a file server (45, Fig. 1-2) such as personal computers having sufficient mass storage (46, Fig. 1-2), such as local hard drives, CD ROM, magnetic tape, or other media (see: column 5, lines 19-22). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50);

(f) the handheld computing device comparing the stored prescribed medication data to the stored patient data and confirming a match between the stored prescribed medication data and the stored patient data is met by the care management system (30, Fig. 2) reading barcode (182, Fig. 5) and patient bracelet (170, Fig. 5A) using a barcode reader to ensure that the right drug is delivered to the right patient at the right time in the right manner (see: column 8, lines 12-19). In addition, care management (30, Fig. 1-2) includes a file server (45, Fig. 1-2) such as personal computers having sufficient mass storage (46, Fig. 1-2), such as local hard drives, CD ROM, magnetic tape, or other media (see: column 5, lines 19-22). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50); and

(g) the handheld computing device communicating the stored medication delivery instruction from the first label to a medication delivery device is met by the care management system (30, Fig. 15) including a pharmacy CPU, the nurse station nursing CPU (70, Fig. 15) and bedside CPUs and clinical devices which are usually connected by Ethernet cabling can be eliminated (see: column 15, lines 35-39). In addition, care management (30, Fig. 1-2) includes a file server (45, Fig. 1-2) such as personal computers having sufficient mass storage (46, Fig. 1-2), such as local hard drives, CD ROM, magnetic tape, or other media (see: column 5, lines 19-22). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50). Engelson et al. also teaches that care management system automatically downloads medication information from the pharmacy CPU (60, Fig. 2) through the local area network (50, Fig. 2) into the bedside CPU (80, Fig. 2) and then into the infusion pump (92, Fig. 2) (see:

column 14, Fig. 2) (see: column 14, lines 4-13). In addition, the infusion pump (92, Fig. 2) can be attached to the bedside CPU (80, Fig. 2) (see: column 14, line 6), suggesting that the infusion pump and bedside CPU are one unit.

(h) the medication delivery device storing the medication delivery instruction and delivering the medication to the patient is met by the care management system (30, Fig. 15) including a pharmacy CPU, the nurse station nursing CPU (70, Fig. 15) and bedside CPUs and clinical devices which are usually connected by Ethernet cabling can be eliminated (see: column 15, lines 35-39). In addition, care management (30, Fig. 1-2) includes a file server (45, Fig. 1-2) such as personal computers having sufficient mass storage (46, Fig. 1-2), such as local hard drives, CD ROM, magnetic tape, or other media (see: column 5, lines 19-22). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50).

As per claim 6, Engelson et al. teaches a method for medication delivery comprising the steps of:

(a) reading medication data contained in a first label on a medication container containing a prescribed medication using a handheld computing device and storing the medication data in the handheld computing device, the first label containing data on the prescribed medication and instruction of delivering of the medication, the prescribed medication data and the instruction of delivering the medication being provided in machine readable format is met by the order

transmitted to the institution's pharmacy which is processed and generally includes the patient's name, the drug name, and the appropriate treatment parameters are represented on the label (182, Fig. 5) affixed to container (see: column 13, lines 3-21). Engleson also teaches that the care management system (30, Fig. 2) reading barcode (182, Fig. 5) and patient bracelet (170, Fig. 5A) using a barcode reader to ensure that the right drug is delivered to the right patient at the right time in the right manner (see: column 8, lines 12-19). In addition, the care management system (30, Fig. 1-2) includes a file server (45, Fig. 1-2) such as personal computers having sufficient mass storage (46, Fig. 1-2), such as local hard drives, CD ROM, magnetic tape, or other media (see: column 5, lines 19-22). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50);

(b) reading patient data contained in a second label on a tag adapted to be worn by a patient using a handheld computing device and storing the patient data in the handheld computing device, the second label containing data of the patient, the patient data being provided in machine readable format is met by the care management system (30, Fig. 2) reading barcode (182, Fig. 5) and patient bracelet (170, Fig. 5A) using a barcode reader to ensure that the right drug is delivered to the right patient at the right time in the right manner (see: column 8, lines 12-19). In addition, the care management system (30, Fig. 1-2) includes a file server (45, Fig. 1-2) such as personal computers having sufficient mass storage (46, Fig. 1-2), such as local hard drives, CD ROM, magnetic tape, or other media (see: column 5, lines 19-22). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians,

nurses or technicians as they circulate through the institution (see: column 15, lines 35-50, column 7, lines 48-51 and Fig. 5A);

(c) the handheld computing device comparing the medication data to the patient data wherein the handheld computing device is met by the care management system (30, Fig. 2) reading barcode (182, Fig. 5) and patient bracelet (170, Fig. 5A) using a barcode reader to ensure that the right drug is delivered to the right patient at the right time in the right manner (see: column 8, lines 12-19). In addition, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50):

means for reading the prescribed medication data and medication delivery instruction from the first label is met by barcodes (182, Fig. 5) and (175, Fig. 5A) being read by barcode reader (68, Fig. 2) (see: column 7, lines 48-54 and column 8, lines 12-19);

means for storing the data and instruction is met by (46, Fig 2) (see: column 19-24); and

means for communicating data and instruction to other electronic devices is met by the file server that includes communication hardware for communicating with the hospital network (see: column 5, lines 25-32);

(d) the handheld computing device confirming the data and communicating the instruction of delivering the stored medication to a medication from the first label to a medication delivery device is met by the care management system (30, Fig. 15) including a pharmacy CPU, the nurse station nursing CPU (70, Fig. 15) and bedside CPUs and clinical devices which are usually connected by Ethernet cabling can be eliminated (see: column 15, lines 35-39). ). In addition, the care management system (30, Fig. 1-2) includes a file server (45,

Fig. 1-2) such as personal computers having sufficient mass storage (46, Fig. 1-2), such as local hard drives, CD ROM, magnetic tape, or other media (see: column 5, lines 19-22). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50).

Engelson et al. also teaches that care management system automatically downloads medication information from the pharmacy CPU (60, Fig. 2) through the local area network (50, Fig. 2) into the bedside CPU (80, Fig. 2) and then into the infusion pump (92, Fig. 2) (see: column 14, Fig. 2) (see: column 14, lines 4-13). In addition, the infusion pump (92, Fig. 2) can be attached to the bedside CPU (80, Fig. 2) (see: column 14, line 6), suggesting that the infusion pump and bedside CPU are one unit.

(h) the medication delivery device storing the medication delivery instruction and delivering the medication to the patient is met by the care management system (30, Fig. 15) including a pharmacy CPU, the nurse station nursing CPU (70, Fig. 15) and bedside CPUs and clinical devices which are usually connected by Ethernet cabling can be eliminated (see: column 15, lines 35-39). In addition, care management (30, Fig. 1-2) includes a file server (45, Fig. 1-2) such as personal computers having sufficient mass storage (46, Fig. 1-2), such as local hard drives, CD ROM, magnetic tape, or other media (see: column 5, lines 19-22). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50). Furthermore, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50).

***Response to Arguments***

5. Applicant's arguments filed 2/6/09 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 2/6/09.

In response to Applicant argument, it is respectfully submitted that the Examiner has applied recited new passages and citations to amended claims 1 and 5-6 at the present time. The Examiner notes that amended limitations were not in the previously pending claims as such, Applicant's remarks with regard to the application of Engleson et al. to the amended limitations are addressed in the above Office Action.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT W. MORGAN whose telephone number is (571)272-6773. The examiner can normally be reached on 9:00 a.m. - 5:30 p.m. Mon - Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Morgan/  
Primary Examiner, Art Unit 3626